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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,244	06/11/2001	James M. Staddon	0623.1090001/EKS/BJD	9543

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/877,244

Applicant(s)

STADDON ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 9-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

A. Claims 1-19 are pending and were subject to restriction in Paper No. 7, dated 9/3/02. In Paper No. 9, filed 11/4/02, Applicants elected Group I, claims 1-4 and 6-8 with traverse and argue that searching Groups II and III in addition to Group I would not impose a serious search burden and that the claims of Groups I-III relate to the signaling pathway initiated by VEGF and, therefore, the same set of publications would have to be searched for all three Groups. These arguments have been considered, but are not deemed persuasive. First, methods of screening for substances would not necessarily overlap a search of the substances per se. If, for example, the method claims of Group I are only made obvious by a combination of references, then the substances may not be disclosed in these individual references. Furthermore, as stated on page 2 of the restriction dated 9/3/02, the invention of Group III does not appear to require VEGF. In addition, Groups I-III are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Therefore, Group I, claims 1-4 and 6-8 are the subject of this Office Action.

2. Information Disclosure Statement

A. Reference AT24 has been lined through since it is not proper subject matter for an IDS. If Applicants wish for this application number to be published and, therefore, publicly available, they are requested to resubmit this reference on a separate IDS stating that they wish to have this reference on the IDS. Applicants can also request that this reference be considered, but not printed on an IDS. However, the application in the IDS must have the same inventors, or be commonly owned.

3. Specification

A. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title, for example, is suggested: A method of screening for substances..."

B. The specification is objected to since it is believed that page 2, line 17 should read "p120/p100 dephosphorylation" instead of "p120/p120 dephosphorylation."

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4. Claim Objections

- A. Claim 4 is objected to since the claim should be amended to recite “any one of claims 1, 2, or 3.”

5. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- A. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite “the use of,” which is non-statutory language. The claims should be amended to recite, for example, “A method of...”

- B. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility. These claims are directed to methods of using VEGF to screen for substances which affect the phosphorylation states of p120 and p100. However, the invention encompassed by these claims has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published 1/5/01, 66 FR 1092. The instant application has provided a description of VEGF, which, itself, has a well-known utility. However, the instant application does not disclose a specific and substantial biological role for the claimed use of this protein. To identify compounds which are involved in dephosphorylation in endothelial cells, for example, is not a specific or substantial use.

Therefore, the instant claims are drawn to a use of a protein which has a yet undetermined function or biological significance. There is no actual and specific significance which can be attributed to said use, other than to affect p11 and p120. However, it is not understood what specific and substantial utility affecting p100 or p120 would have. For this reason, the instant invention is incomplete. In the absence of a knowledge of the significance of this use, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which bind to and/or mediate activity of other non-specific proteins (p100/p120) is clearly to use it as the object of further research which has been determined by the courts to be a non-patentable utility. Since the instant specification does not disclose a “real-world” use for said use then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. If Applicants assert that there is a utility for this use, they are required to point out exactly where in this specification there is support.

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 1-4 and 6-8 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: methods of how to perform the claimed screening method, including a sequential order of step as well as recitation of the proper controls and a conclusion step which demonstrates that the claimed method has been completed.

8. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Esser et al. (J. Cell Science 111:1853-1865, 1998). The claims recite the use of VEGF to screen for substances which affect phosphorylation of p100 or p120. Esser teach that VEGF induces phosphorylation of p120 (Abstract) and Esser teach the use of various compounds in mediating this phosphorylation (see "Discussion"). Esser use compounds such as PIGF and PIGF152 in these studies to determine their effects on phosphorylation;

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hence, screening compounds. The reference is silent as to whether or not serine or threonine residues are (de)phosphorylated. Therefore, since p100/p120 contain these residues, it would be expected that, in absence of evidence to the contrary, these residues would be (de)phosphorylated.

B. Claims 1-4 are rejected under 35 USC 102(e) as being anticipated by Staddon et al. (US Patent 6,312,686). The claims recite the use of VEGF to screen for substances which affect phosphorylation of p100 or p120. Staddon et al teach tight junction permeability, such as that found in the blood brain barrier, is influenced by adherins (column 6, lines 17-30) and that there is a link between p100/p120 and adherin junction proteins (column 11, line 66 – column 12, line 18). Staddon also teach that these tight junctions are also dependent on tyrosine kinase activity and that VEGF activates tyrosine kinase and that blockers of these activators could be useful in stroke therapy (column 13, line 56 – column 14, line 52). Given the teachings of Staddon, one of ordinary skill in the art would immediately envision screening compounds to find blockers of VEGF. The reference is silent as to whether or not serine or threonine residues are (de)phosphorylated. Therefore, since p100/p120 contain these residues, it would be expected that, in absence of evidence to the contrary, these residues would be (de)phosphorylated.

9. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Esser et al. or Staddon et al. each in view of Ratcliffe et al. (J. Biol. Chem. 272:31894-31901, 1997). The claims recite the use of VEGF to screen for substances which affect phosphorylation of p100 or p120. The teachings of Esser and Staddon are seen in the above rejection under 35 USC 102. Neither Esser nor Staddon teach a PKC pathway. However, Ratcliffe do teach that p100/p120 are dephosphorylated in response to PKC activation. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the present invention to have performed a screening assay using VEGF and a PKC pathway to screen for competitors and activators of VEGF. The reference is silent as to whether or not serine or

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threonine residues are (de)phosphorylated. Therefore, since p100/p120 contain these residues, it would be expected that, in absence of evidence to the contrary, these residues would be (de)phosphorylated.

10. Obviousness-Type Double Patenting

A. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 1-4 and 6-8 provisionally rejected under the judicially created doctrine of double patenting over all claims of copending Application No. 10/349,111 and 10/349,074. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: these cases are new and have not been restricted. Therefore, any subject matter that would be considered double patenting should be addressed in the response. If Applicants do not feel comfortable doing this, they are requested to send in a copy of the pending claims in order for the Examiner to make a judgement.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

9. Conclusion

A. No claim is allowable.

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Advisory information

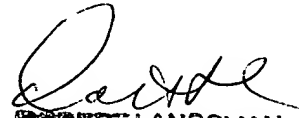
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
June 29, 2003



ROBERT LANDSMAN
PATENT EXAMINER